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UNITED STATES DEPARTMENT OF COMMERCE
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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

#10

Dear Mr. Wilson:

The attached application for patent term extension¹ of U.S. Patent No. 4,962,098, was filed on November 21, 1996, under 35 U.S.C. § 156. U.S. Patent No. 4,962,098 issued on October 9, 1990 from an application that claimed priority to an application filed on October 9, 1984. Accordingly, the original expiration date of the patent is October 9, 2007.

The assistance of your Office is requested in confirming that the product identified in the application, ESTROSTEP® (norethindrone acetate and ethinyl estradiol), has been subject to a regulatory review period under § 505(b) of the Federal Food, Drug and Cosmetic Act (FFDCA) within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 if both of the active ingredients, norethindrone acetate and ethinyl estradiol, were previously approved under § 505 of the FFDCA. In re Alcon Laboratories, 13 USPQ2d 1115 (Com'r Pats 1989).

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Charles W. Ashbrook/Assistant General Counsel
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2800 Plymouth Road
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¹It is noted that the structural formulas were omitted from page 2 of the application, but that they are shown in Exhibit 1, the package insert.